

## REMARKS

All the claims submitted for examination in this application have been rejected on formal and/or substantive grounds. Applicant has amended her claims and respectfully submit that all the claims currently in this application are patentable over the rejection of record.

Turning first to the formal grounds of rejection, three separate formal grounds of rejection are imposed in the outstanding Official Action. The first of these is directed to Claim 1, which stands rejected, under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The Official Action avers that Claim 1 contains subject matter which is not described in the specification in such a way as to reasonably convey, to one skilled in the relevant art, that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient descriptive support for the phrase “treating an age-related behavioral disorder.”

In supporting this ground of rejection the Official Action argues that there is insufficient description of an “age-related behavioral disorder.” Specifically, the Official Action argues that the only specific age-related behavioral disorder mentioned in the specification is cognitive dysfunction syndrome.

It is axiomatic that a written description must describe limitations of a claim with sufficient clarity and specificity so that persons of ordinary skill in the art will recognize from the disclosure that the patentees had invented the invention defined by the claims. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). The primary consideration is factual and depends on the nature of the invention and the amount of knowledge imparted to

those skilled in the art by the disclosure. ibid. The written description requirement does not require an exact description of the subject matter claimed. Rather, the description must clearly allow persons of ordinary skill in the art to recognize that the patentees invented what is claimed. In re Gosteli, 872 F2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Applicant submits that these tests are clearly met by the disclosure of the instant specification. Therein it is recited that age-related behavioral disorders include cognitive dysfunction syndrome (CDS). This much the Official Action admits. However, the Official Action argues that other conditions associated with age-related behavioral disorders are not disclosed.

Applicant respectfully argues that although the specification is imperfectly recited, it is clear that other conditions commonly referred to as an age-related behavioral disorder are set forth therein. Specifically, such conditions as depression, anxiety and generally decreased health are also mentioned. CDS, by its definition, involves cognition. That cognition means the process of knowing in the broadest sense thus includes perception, memory, judgment, and the like. Cognition clearly does not encompass depression or anxiety. Those skilled in the art, however, are quite aware that these conditions, along with CDS, are well established age-related behavioral disorders. As such, the generic term “age-related behavioral disorders,” is supported by more than an important example of these disorders, CDS. Reconsideration and removal of this ground of rejection, in view of the aforementioned remarks, is therefore deemed appropriate. Such action is respectfully urged.

The second formal ground of rejection is directed to Claims 3-8. These claims stand rejected, under 35 U.S.C. §112, second paragraph, as being indefinite.

Claims 3-8 stand rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention insofar as each of these independent claims refer to a compound of Formula I. However, the definition of Formula I is not provided in any of these claims.

This ground of rejection is well taken. To overcome this formal ground of rejection applicant has cancelled each of Claims 3-8 and replaced them with new Claims 22-27, respectively. New Claims 22-27 are identical with the claims replaced, Claims 3-8 respectively, but for the inclusion in the new claims of the definition of Formula I. Applicant submits that the amendment to Claims 3-8, as new Claims 22-27, overcomes the second formal ground of rejection imposed in the outstanding Official Action.

The third formal ground of rejection is directed to Claim 4. Claim 4 stands rejected, under 35 U.S.C. §112, second paragraph, as being indefinite. The phrase “sufficient to improve cognitive processing,” as suggested in the Official Action, is somewhat inconsistent with a method of treating memory loss. As such, new Claim 23, which replaces Claim 4, does not include the aforementioned objected to phrase. Applicants submit that the removal of this phrase overcomes the ground of rejection imposed in the separate rejection of Claim 4.

Two substantive grounds of rejection are imposed in the outstanding Official Action. The first of these is directed to all the claims pending in this application, Claims 1-9, 11, 12 and 17-21. These claims stand rejected, under 35 U.S.C. §103(a), as being unpatentable over U.S. Patent 5,494,908 to O’Malley et al.

O’Malley et al. teaches benzisoxazole compounds which are anticholinesterase inhibitors effective in the treatment of Alzheimer’s disease. The Official Action avers that the O’Malley et al. teaching of pharmaceutical preparations of benzisoxazole compounds recited

therein possess identical benzisoxazolyl and piperidenyl moieties and other identical substituents as the compound set forth in the claims of the present application.

Although the Official Action argues that the compounds of O’Malley et al. and the claims of the present application are both anticholinesterase inhibitors, the Official Action admits that the linking group, denoted by Y in the claims of the present application, are not duplicated by the O’Malley et al. compounds. Whereas Y is  $-(CH_2)_m-$ ,  $-CH=CH(CH_2)_n-$  or  $-O(CH_2)_m-$ , where n is an integer of from 0 to 3 and m is an integer of 1 to 3, the linking group in the O’Malley et al. compounds is a nitrogen atom.

The suggestion that it would be obvious to substitute a hydrocarbyl or an oxyhydrocarbyl moiety for the aminohydrocarbyl moiety of O’Malley et al. is rebutted by the absence of any disclosure in O’Malley et al. suggesting the utility of the present application therein. That is, there is no disclosure, suggestion or even hint that an age-related behavioral disorder in a companion animal is within the contemplation of the utility of the compounds taught in the applied O’Malley et al. patent.

In summary, the strong structural dissimilarity between the compounds within the scope of O’Malley et al. and those claimed herein is magnified by the absence of any common utility between the compounds recited in the method claims of the present application and those taught in the O’Malley et al. patent.

As stated above, there is no discussion of any use of the compounds disclosed in O’Malley et al. in the treatment of a companion animal. The emphasis on Alzheimer’s disease in O’Malley et al. establishes this clear line of distinction. There is no documentation of Alzheimer’s disease in companion animals. Alzheimer’s disease is a condition exclusively associated with human beings.

To summarize the above remarks, all the claims of the present application are directed to a method of treating conditions existent in companion animals utilizing compounds having a generic chemical structural formula dissimilar from the compounds disclosed in the applied O’Malley et al. reference. That O’Malley et al. does not utilize the structurally dissimilar compounds in treatment of companion animals only emphasizes the unobviousness of the claims of the present application. Reconsideration and removal of this ground of rejection is therefore deemed appropriate. Such action is respectfully urged.

The second substantive ground of rejection is the rejection of Claims 1-9, 11, 12 and 17-21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 and 2 of U.S. 5,538,984 to Villalobos et al.

The test of viability of this ground of rejection is whether the disclosure of Claims 1 and 2 of Villalobos et al. make obvious Claims 1-9, 11, 12 and 17-21 of the present application. Applicant concedes that the compounds of Claims 1 and 2 of Villalobos et al. emulate those recited in the claims of the present application. However, the method of the claims of the present application are at odds with the teaching of Claims 1 and 2 of Villalobos et al. Claim 2 is directed to a method of enhancing memory or treating Alzheimer’s disease in a mammal comprising administering to said mammal a memory enhancing or Alzheimer’s disease treating or preventing amount of the recited generic compound. Similarly, Claim 1 of Villalobos et al. discloses this utility by administering an acetylcholinesterase inhibiting effective amount of the compound to a mammal. Insofar as Alzheimer’s disease is not a disease known in companion animals, Claims 1-9, 11, 12 and 17-21 of the present application would not be obvious to one of ordinary skill in the art based on the disclosure of Claim 1 or 2 of Villalobos et al.

Applicant appreciates that it may be argued that the disclosure of Claim 1 of a method of enhancing memory or treating Alzheimer's disease in a mammal, by administering an acetylcholinesterase inhibiting effective amount of the claimed compound, would apply to companion animals which, of course, are mammals. However, an aectylcholinesterase inhibiting amount has only been shown, based on the specification in Villalobos et al., to be effective in enhancing cholinergic activity, and thus improving the memory of Alzheimer's disease patients, who are human beings, not companion animals.

Similarly, the administration of a memory enhancing or Alzheimer's disease treating or preventing effective amount of the recited compound of Claim 2 must, in the absence of a teaching of Alzheimer's disease in companion animal, be deemed to be relevant to only one class of mammals, human beings.

It is axiomatic that a claim is interpreted in a manner consistent with its validity. Whittaker Corp. v. UNR Indus., Inc., 911 F.2d 709, 712, 15 USPQ 2d 1742, 1744 (Fed. Cir. 1990). Thus, in order to sustain the validity of Claims 1 and 2 in Villalobos et al., it is essential to interpret those claims so that "mammals" is interpreted as being limited to the mammal species, human beings. In the absence of that interpretation the claims could be held invalid on the ground that many species of mammals do not suffer from Alzheimer's disease and thus the claim would include too many inoperative embodiments.

In view of these remarks it is apparent that Claims 1 and 2 of Villalobos et al. does not make obvious any of the claims of the present application, given the fact that all the claims of the present application are limited to companion animals.

It is emphasized that the recitation, in the outstanding Official Action, of material taken from the specification of Villalobos et al. is improper. A rejection under the judicially

created doctrine obvious-type double patenting excludes utilization of the specification of the applied patent. Under this doctrine only the teaching in the claims is available as a reference. The allegation that dementia, as well as Alzheimer's disease, are commonly associated with disorders afflicting older mammals, presumably including companion animals, is unsustained by such recitation in Claims 1 and 2 of Villalobos et al. As such, this disclosure is not prior art under this ground of rejection.

The above amendment and remarks establish the patentable nature of all the claims currently in this application. Notice of Allowance and passage to issue of these claims, Claims 1, 2, 9, 11, 12 and 17-27, is therefore respectfully solicited.

Respectfully submitted,



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